CONTRACT CONCEPT REVIEW

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Concept Title: **Analytical Chemistry Support for NTP**

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Purpose

The purpose of these contracts is to provide analytical chemistry support for toxicology bioassays and *in vitro* assays conducted by the National Toxicology Program (NTP). The analytical services are necessary to ensure that the studies are conducted with the intended test articles (confirmation of identity and purity), at specified dosages (dose formulation, stability, and dose analysis), and with the knowledge of biomarkers of exposure and effect, internal dose, and tissue dosimetry.

Background and Concept Statement

Major efforts to be performed under these contracts are method development, chemical procurement, bulk chemical characterization, dosage formulation, formulation analysis, biological sample analysis, toxicokinetic studies, and shipping of materials to bioassay contractors and other organizations. Procurements are usually made through commercial sources, although when required, custom syntheses are arranged through commercial synthesis laboratories. Once received, characterization of the test article is performed, not only to verify identity but also to distinguish any impurities that might confound interpretation of the toxicology results. An abbreviated chemical identity and purity screen is used for studies that include many compounds tested as a set (high- and medium-throughput screening as examples). Special investigations to determine the identity and concentration of low-level impurities may also be conducted. Formulation and formulation analysis methods are developed specifically for test articles and validated for use to ensure that the exposures cited in bioassays are valid. Also, increasingly, it is important to supplement exposure data with toxicokinetic measurements of elimination rate and internal dose. This information is vital to ensure that toxicological evaluations can be used in developing scientifically valid toxicity information and risk assessment. Finally, biochemical measurements such as biomarkers of exposure and effect are developed and conducted to help elucidate mechanistic aspects of specific NTP studies.

The extensive level of effort, facilities requirements, and analytical throughput required for the support of the collective carcinogenicity, general toxicology, reproductive and developmental toxicology, immunology, neurotoxicology, cellular and genetic toxicology, and AIDS therapeutics studies conducted by NTP required the award of three chemistry support contracts in the last procurement. Up to three awards are anticipated under this recompetition.

Proposed Changes to the Current Statement of Work

The work to be performed under the recompetition is essentially the same as described above. The period of performance has been expanded to 5 base years with 3 option years.